

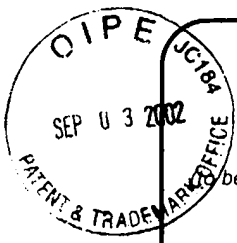
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Application Number		10/038,060 (Parent: 08/973,823)
Filing Date		January 4, 2002
First Named Inventor		Andrew Koff et al.
Group Art Unit		1632 (Parent GAU: 1632)
Examiner Name		Unassigned (Parent Ex: R. Shukla)
Total Number of Pages in This Submission	1	Attorney Docket Number
		14538A-005111US

ENCLOSURES (check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Mark G. Sandbaken, Ph.D.		Reg. No. 39,354
Signature	<i>M. G. Sandbaken</i>		
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PATENT
Attorney Docket No. 14538A-005111US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

ANDREW KOFF et al.

Application No.: 10/038,060
Parent Application No.: 08/973,823

Filed: January 4, 2002

For: METHODS FOR ENHANCING
ANIMAL GROWTH AND CELL
PROLIFERATION BY
ELIMINATION OF THE CYCLIN-
DEPENDENT KINASE
INHIBITOR FUNCTION OF
P27^{Kip1}

Examiner: Unassigned
Parent Examiner: R. Shukla

Art Unit: 1632
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Assistant Commissioner for Patents
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Dear Sir:

Applicants direct the Examiner's attention to the references below, also listed on the accompanying Form PTO-1449. Copies were provided in the parent application (USSN 08/973,823) and therefore are not enclosed herewith pursuant to 37 CFR 1.98(d), unless otherwise indicated. Documents not previously cited are marked with an asterisk, and copies are enclosed.

The following U.S. Patents are set forth below by issue date:

- AA. U.S. Patent 5,302,706 issued April 12, 1994 to Smith et al.*
- AB. U.S. Patent 5,340,740 issued August 23, 1994 to Petite et al.*
- AC. U.S. Patent 5,650,550 issued July 22, 1997 to Korach et al.
- AD. U.S. Patent 5,958,769 issued September 28, 1999 to Roberts et al.

The following international publications are set forth by publication date:

- AE. PCT Publication No. WO 94/26884 published on November 24, 1994.*
- AF. PCT Publication No. WO 95/18824 published on July 13, 1995.*
- AG. PCT Publication No. WO 96/02140 published on February 1, 1996.*
- AH. PCT Publication No. WO 97/26327 published on July 24, 1997.*
- AI. PCT Publication No. WO 97/38091 published on October 16, 1997.*

The following articles are set forth by the indicated year of publication date:

- AJ. Capecchi, "High Efficiency Transformation by Direct Microinjection of DNA into Cultured Mammalian Cells," Cell 22:479-488 (November, 1980).*
- AK. Thomas et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells," Cell 51:503-512 (November 6, 1987).*
- AL. Doetschman et al., "Targetted Correction of a Mutant HPRT Gene in Mouse Embryonic Stem Cells," Nature 330:576-578 (December 10, 1987).*
- AM. Doetschman et al., "Establishment of Hamster Blastocyst-Derived Embryonic Stem (ES) Cells," Devel. Biol. 127:224-227 (May 1, 1988).*
- AN. Thomas et al., "Targeted Disruption of the Murine *int-1* Proto-Oncogene Resulting in Severe Abnormalities in Midbrain and Cerebellar Development," Nature 346:847-850 (August 30, 1990).*
- AO. Shulman et al., "Homologous Recombination in Hybridoma Cells: Dependence on Time and Fragment Length," Mol. Cell. Biol. 10:4466-4472 (September 1990).*
- AP. Rahemtulla et al., "Normal Development and Function of CD8⁺ Cells but Markedly Decreased Helper Cell Activity in Mice Lacking CD4," Nature 353:180-184 (September 12, 1991).*
- AQ. Hasty et al., "Target Frequency and Integration Pattern for Insertion and Replacement Vectors in Embryonic Stem Cells," Mol. Cell. Biol. 11:4509-4517 (September 1991).*
- AR. Houdebine et al., "Transgenesis in Fish," Experientia 47:891-897 (1991).*

AS. Donehower et al., "Mice Deficient for p53 are Developmentally Normal but Susceptible to Spontaneous Tumours," Nature 356:215-221 (March 19, 1992).*

AT. Sorrentino et al., "Selection of Drug-Resistant Bone Marrow Cells in Vivo After Retroviral Transfer of Human *MDR1*," Science 257:99-103 (July 3, 1992).*

AU. Koff et al., "Formation and Activation of a Cyclin E-cdk2 Complex During the G₁ Phase of the Human Cell Cycle," Science 257:1689-1694 (September 18, 1992).*

AV. Baker et al., "Osteoblast-Specific Expression of Growth Hormone Stimulates Bone Growth in Transgenic Mice," Mol. Cell. Biol. 12:5541-5547 (December 1992).*

AW. Sukoyan et al., "Isolation and Cultivation of Blastocyst-Derived Stem Cell Lines from American Mink (*Mustela Vison*)," Mol. Rep. Dev. 33:418-431 (December 1992).*

AX. Bradley et al., "Modifying the Mouse: Design and Desire," Biotechnology 10:534-539 (1992).*

AY. Kappel et al., "Regulating Gene Expression in Transgenic Animals," Current Opinion in Biotechnology 3:548-553 (1992).*

AZ. Ohtsubo et al., "Cyclin-Dependent Regulation of G₁ in Mammalian Fibroblasts," Science 259:1908-1912 (March 26, 1993).*

BA. Koff et al., "Negative Regulation of G₁ in Mammalian Cells: Inhibition of Cyclin E-Dependent Kinase by TGF- β ," Science 260:536-539 (April 23, 1993).

BB. Schaffner et al., "Targeting of the *rasT24* Oncogene to the Proximal Convulated Tubules in Transgenic Mice Results in Hyperplasia and Polycystic Kidneys," American Journal of Pathology 142:1051-1060 (April 1993).*

BC. Nakayama et al., "Disappearance of the Lymphoid System in Bcl-2 Homozygous Mutant Chimeric Mice," Science 261:1584-1588 (September 17, 1993).*

BD. Ewen et al., "TGF β Inhibition of Cdk4 Synthesis is Linked to Cell Cycle Arrest," Cell 74:1009-1020 (September 24, 1993).

BE. Huang et al., "Cellular Interactions Implicated in the Mechanism of Photoreceptor Degeneration in Transgenic Mice Expressing a Mutant Rhodopsin Gene," Proc. Nat. Acad. Sci. USA 90:8484-8488 (September 1993).*

BF. Mullins et al., "Transgenesis in Nonmurine Species," Hypertension 22:630-633 (October 1993).

BG. Serrano et al., "A New Regulatory Motif in Cell-Cycle Control Causing Specific Inhibition of Cyclin D/CDK4," Nature 366:704-707 (December 16, 1993).*

BH. Graves et al., "Derivation and Characterization of Putative Pluripotential Embryonic Stem Cells from Preimplantation Rabbit Embryos," Mol. Rep. Dev. 36:424-433 (1993).*

BI. Polyak, "p27^{KIP1}, a Cyclin-Cdk Inhibitor, Links Transforming Growth Factor- β and Contact Inhibition to Cell Cycle Arrest," Genes & Development 8:9-22 (January 1994).

BJ. Iannaccone et al., "Pluripotent Embryonic Stem Cells from the Rat Are Capable of Producing Chimeras," Devel. Biol. 163:288-292 (May 1, 1994).*

BK. Kaushansky et al., "Promotion of Megakaryocyte Progenitor Expansion and Differentiation by the c-Mpl Ligand Thrombopoietin," Nature 369:568-571 (June 16, 1994).*

BL. Slingerland et al., "A Novel Inhibitor of Cyclin-Cdk Activity Detected in Transforming Growth Factor β -Arrested Epithelial Cells," Mol. Cell. Biol. 14:3683-3694 (June 1994).

BM. Polyak et al., "Cloning of p27^{KIP1}, a Cyclin-Dependent Kinase Inhibitor and a Potential Mediator of Extracellular Antimitogenic Signals," Cell 78:59-66 (July 15, 1994).

BN. Toyoshima et al., "p27, a Novel Inhibitor of G1 Cyclin-Cdk Protein Kinase Activity, Is Related to p21," Cell 78:67-74 (July 15, 1994).

BO. Firpo et al., "Inactivation of a Cdk2 Inhibitor During Interleukin 2-Induced Proliferation of Human T-Lymphocytes," Mol. Cell. Biol. 14:4889-4901 (July 1994).*

BP. Jiang et al., "Induction of differentiation in Human Promyelocytic HL-60 Leukemia Cells Activates p21, WAF1/CIP1, Expression in the Absence of p53," Oncogene 9:3397-3406 (November 1994).

BQ. Steinman et al., "Induction of p21 (WAF-1/CIP1) During Differentiation," Oncogene 9:3389-3396 (November 1994).

BR. Zhuang et al., "The Helix-Loop-Helix Gene E2A is Required for B Cell Formation," Cell 79:875-884 (December 2, 1994).*

BS. Nourse et al., "Interleukin-2-Mediated Elimination of the p27^{Kip1} Cyclin-Dependent Kinase Inhibitor Prevented by Rapamycin," Nature 372:570-573 (December 8, 1994).*

BT. Kato et al., "Cyclic AMP-Induced G1 Phase Arrest Mediated by an Inhibitor (p27Kip1) of Cyclin Dependent Kinase 4 Activation," Cell 79:587:487-496 (1994).*

BU. Seamark, "Progress and Emerging Problems in Livestock Transgenesis: a Summary Perspective," Reprod. Fertil. Dev. 6:653-657 (1994).

BV. Wakamatsu et al., "Establishment of a Pluripotent Cell Line Derived from a Medaka (*Oryzias Latipes*) Blastula Embryo," Molecular Marine Biology and Biotechnology 3:185-191 (1994).*

BW. Wheeler, "Development and Validation of Swine Embryonic Stem Cells: a Review," Reprod. Fertil. Dev., 6:563-568 (1994).*

BX. Wigley et al., "Site-Specific Transgene Insertion: an Approach," Reprod. Fertil. Dev. 6:585-588 (1994).*

BY. Raviprakash et al., "Inhibition of Dengue Virus by Novel, Modified Antisense Oligonucleotides," J. Virol. 69:69-74 (January 1995).*

BZ. Peitenpol et al., "Assignment of the Human p27^{Kip1} Gene to 12p13 and Its Analysis in Leukemias," Can. Res. 55:1206-1210 (March 15, 1995).*

CA. Ravitz et al., "Transforming Growth Factor β -Induced Activation of Cyclin E-cdk2 Kinase and Down-Regulation of p27^{Kip1} in C3H 10T^{1/2} Mouse Fibroblasts," Can. Res. 55:1413-1416 (April 1, 1995).*

CB. Sherr et al., "Inhibitors of Mammalian G₁ Cyclin-Dependent Kinases," Genes & Development 9:1149-1163 (May 15, 1995).

CC. Chan et al., "Identification of Human and Mouse p19, a Novel CDK4 and CDK6 Inhibitor with Homology to p16^{ink4}," Mol. Cell. Biol. 15:2682-2688 (May 1995).*

CD. Resnitzky et al., "Different Roles for Cyclins D1 and E in Regulation of the G₁-to-S Transition," Mol. Cell. Biol. 15:3463-3469 (July 1995).*

CE. Reynisdottir et al., "Kip/Cip and Ink4 Cdk Inhibitors Cooperate to Induce Cell Cycle Arrest in Response to TGF- β ," Genes & Development 9:1831-1845 (August 1, 1995).

CF. Pagano et al., "Role of Ubiquitin-Proteasome Pathway in Regulating Abundance of the Cyclin-Dependent Kinase Inhibitor p27," Science 269:682-685 (August 4, 1995).

CG. Thomson et al., "Isolation of a Primate Embryonic Stem Cell Line," Proc. Nat. Acad. Sci. USA 92:7844-7848 (August 15, 1995).*

CH. Deng et al., "Mice Lacking p21^{CIP1/WAF1} Undergo Normal Development, but Are Defective in G1 Checkpoint Control," Cell 82:675-684 (August 25, 1995).*

CI. Brugaroias et al., "Radiation-Induced Cell Cycle Arrest Compromised by p21 Deficiency," Nature 377:552-557 (October 12, 1995).*

CJ. Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science 270:404-410 (October 20, 1995).

CK. Khare et al., "Spontaneous Inflammatory Arthritis in HLA-B27 Transgenic Mice Lacking β_2 -Microglobulin: A Model of Human Spondyloarthropathies," J. Exp. Med. 182:1153-1158 (October 1995).*

CL. Kranenburg et al., "Inhibition of Cyclin-Dependent Kinase Activity Triggers Neuronal Differentiation of Mouse Neuroblastoma Cells," J. Cell Biol. 131:227-234 (October 1995).

CM. Koff et al., "p27^{KIP1}, an Inhibitor of Cyclin-Dependent Kinases," Progress in Cell Cycle Research 1:141-147 (1995).

CN. Li et al., "mRNA Expression of Vimentin Gene in Lens of Transgenic Mouse and DNA Amplification in Human Cataracts," Eye Science 11:113-116 (1995).*

CO. Limonta et al., "Production of Active Anti-CD6 Mouse/Human Chimeric Antibodies in the Milk of Transgenic Mice," Immunotechnology 1:107-113 (1995).*

CP. Stull et al., "Antigene, Robozmye and Aptamer Acid Drugs: Progress and Prospects," Pharma. Res. 12:465-483 (1995).*

CQ. van Denderen et al., "Expression of Functional Decay-Accelerating Factor (CD55) in Transgenic Mice Protects Against Human Complement-Mediated Attack," Transplantation 61:582-588 (February 27, 1996).*

CR. Campbell et al., "Sheep Cloned by Nuclear Transfer from a Cultured Cell Line," Nature 380:64-66 (March 7, 1996).*

CS. Mullins et al., "Perspectives Series: Molecular Medicine in Genetically Engineered Animals, Transgenesis in the Rat and Larger Mammals," J. Clin. Invest. 97:1557-1560 (April 1996).

CT. Coats et al., "Requirement of p27^{Kip1} for Restriction Point Control of the Fibroblast Cell Cycle," Science 272:877-880 (May 10, 1996).*

CU. Fero et al., "A Syndrome of Multiorgan Hyperplasia with Features of Gigantism, Tumorigenesis, and Female Sterility in p27^{Kip1}-Deficient Mice," Cell 85:733-744 (May 31, 1996).*

CV. Kiyokawa et al., "Enhanced Growth of Mice Lacking the Cyclin-Dependent Kinase Inhibitor Function of p27^{Kip1}," Cell 85:721-732 (May 31, 1996).*

CW. Nakayama et al., "Mice Lacking p27^{Kip1} Display Increased Body Size, Multiple Organ Hyperplasia, Retinal Dysplasia, and Pituitary Tumors," Cell 85:707-720 (May 31, 1996).*

CX. Tyers, "The Cyclin-Dependent Kinase Inhibitor p40^{SIC1} Imposes the Requirement for Cln G1 Cyclin Function at Start," Proc. Nat. Acad. Sci. USA, 93:7772-7776 (July 1996).*

CY. Rivard et al., "Abrogation of p27^{Kip1} by cDNA Antisense Suppresses Quiescence (G₀ State) in Fibroblasts," J. Biol. Chem. 271:18337-18341 (August 2, 1996).*

CZ. Ross et al., "Gene Therapy in the United States: A Five-Year Status Report," Human Gene Therapy 7:1781-1790 (September 10, 1996).*

DA. Irwin et al., "Identification of Transgenic Mice by PCR Analysis of Saliva," Nature Biotechnology 14:1146-1148 (September 1996).*

DB. Schoonjans et al., "Pluripotential Rabbit Embryonic Stem (ES) Cells Are Capable of Forming Overt Coat Color Chimeras Following Injection into Blastocysts," Mol. Rep. Dev. 45:439-443 (September 1996).*

DC. Khare et al., "HLA-B27 Heavy Chains Contribute to Spontaneous Inflammatory Disease in B27/Human β_2 -Microglobulin (β_2m) Double Transgenic Mice with Disrupted Mouse β_2m ," J. Clin. Invest. 98:2746-2755 (December 1996).*

DD. Charreau et al., "Transgenesis in Rats: Technical Aspects and Models," Trans. Res. 5:223-234 (1996).*

DE. Liu et al., "Transcriptional Activation of the Cdk Inhibitor p21 by Vitamin D₃ Leads to the Induced Differentiation of the Myelomonocytic Cell Line U937," Genes & Development 10:142-153 (1996).

DF. Mullins et al., "Perspectives Series: Molecular Medicine in Genetically Engineered Animals, Transgenesis in the Rat and Larger Mammals," J. Clin. Invest. 98:S37-S40 (1996).

DG. Rojanasakul, "Antisense oligonucleotide therapeutics: drug delivery and targeting," Y. Advanced Drug Delivery Reviews 18:115-131 (1996).*

DH. Campbell et al., "Totipotency or Multipotentiality of Cultured Cells: Applications and Progress," Theriogenology 47:63-72 (January 1, 1997).*

DI. Cameron, "Recent Advances in Transgenic Technology," Molecular Biotechnology 7:253-265 (1997).

DJ. Gardner et al., "Reflections on the Biology of Embryonic Stem (ES) Cells," Int. J. Dev. Biol. 41: 235-243 (1997).

DK. Merriam Webster's Collegiate Dictionary, "Bull," 10th Ed., pg. 150. (1997).

DL. Merriam Webster's Collegiate Dictionary, "Cow," 10th Ed., pg. 268 (1997).

DM. Moreadith et al., "Gene Targeting in Embryonic Stem Cells: the New Physiology and Metabolism," J. Mol. Med. 75:208-216 (1997).

DN. Hong et al., "Production of Medakafish Chimeras from a Stable Embryonic Stem Cell Line," Proc. Nat. Acad. Sci. USA 95:3679-3684 (March 31, 1998).*

DO. Anderson, "Human Gene Therapy," Nature 392 (supp.):25-30 (April 30, 1998).

DP. Deonarain, "Ligand-Targeted Receptor-Mediated Vectors for Gene Delivery," Exp. Opin. Ther. Patents 8:53-69 (1998).

DQ. Khare et al., "Unraveling the Mystery of HLA-B27 Association with Human Spondyloarthropathies Using Transgenic and Knock Out Mice," Immunology 10:15-23 (1998).*

DR. Mountain, "Gene Therapy: the First Decade," Tibtech 18:119-128 (March, 2000).*

DS. Sigmund, "Viewpoint: Are Studies in Genetically Altered Mice Out of Control?," Arterioscler Thromb. Vasc. Biol. 20:1425-1429 (June 2000).

DT. Denning et al., "Deletion of the α (1,3) Galactosyl Transferase (*GGT1*) Gene and the Prion Protein (*PrP*) Gene in Sheep," Nature Biotechnology 19:559-562 (June 2001).*

Applicants also notify the Examiner of co-pending Application No: 09/637,848, filed August 10, 2000, in the name of Roberts *et al.*, which Applicants believe is cumulative with reference AD (U.S. Patent No. 5,958,769; Roberts *et al.*) and reference AH (PCT Publication WO 97/26327). These references are not commonly assigned, or under an obligation to be commonly assigned, with the instant application.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. However, Applicants reserve the right to demonstrate that the claimed invention was made prior to any one or more of the above-identified references. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

Andrew Koff et al.
Application No.: 10/038,060
Parent Appl. No.: 08/973,823
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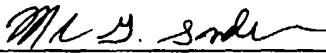
PATENT

Applicants respectfully request that the Examiner review the foregoing references to make his/her own determination of the patentability of the present invention and that the references be made of record in the file of this application.

This Information Disclosure Statement is being filed before the mailing date of the first Office Action. Although no fee is believed to be due, the Commissioner is hereby authorized to charge any fees necessitated by this transmittal to Townsend and Townsend Deposit Account No. 20-1430.

Respectfully submitted,

Dated: 8/28/02

By: 
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